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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,571	07/25/2003	Usha Kasid	223316	4233
23460	7590	08/23/2005	EXAMINER	
LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6780			ASHEN, JON BENJAMIN	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/627,571

Applicant(s)

KASID ET AL.

Examiner

Jon B. Ashen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 13, 14, 16-20 and 43-61 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 16-20 and 43-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10 is/are rejected.
- 7) ☒ Claim(s) 1-8 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/03/2004/5/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: NCFI Printout.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, in the reply filed on 04/15/2005, is acknowledged. The traversal is on the ground(s) that as amended, the currently presented claims link each of the separate groups identified in the Office Action, mailed 3/15/2005 and that accordingly, pursuant to MPEP §809.03, the claims should be examined together. This is not found persuasive because, contrary to Applicant's arguments, the amendments do not link the restricted inventions as set forth in to MPEP §809.03. Newly presented claim 50 is drawn to a method of detecting cancer using a polynucleotide of claim 7 or the antibody of claim 19. Newly presented claim 50, therefore, links methods of detecting cancer that would employ either a nucleic acid or an antibody. Group I, as set forth in the requirement for restriction, is drawn to a composition that is a polynucleotide. This composition is not therefore linked to group IX by claim 50 in part because, as a method, claim 50 would link patentably distinct methods requiring the use of nucleic acids or antibodies, but does not link claims to a composition, which would be patentably distinct from the method based on a product and process of use relationship, as was set forth and properly restricted in the Action mailed 3/15/2005 (see pg. 7, section 6). Similarly, Group I is not linked to Group IV by claim 45 because claim 45 is a method and is patentably distinct from the product claimed in Group I and is properly restricted because the product can be used in materially different process of using that product which would be a method of detecting

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cell or tissue specific gene expression. Groups I is not linked to Group II by claims 13-18 because these inventions are unrelated as set forth on pg. 5, section 3 of the Action mailed 3/15/05. It is noted here that claim 15, which is cancelled in the instant application, is referred to in the above argument but was probably not intended to be included. Subsequent arguments concerning linked groups I and II are therefore moot as the restriction between groups I and II is proper.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Application

2. Claims 1-8, 10, 13-14, 16-20 and 43-61 are pending in this application. Claims 9, 11-12, 15 and 21-42 were cancelled by Applicant in the communication filed 4/15/05. Claims 13-14, 16-20 and 43-61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/15/05.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on 7/25/2003 and 5/31/2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner. However, references II, JA, which appear on the IDS filed 5/31/2005, could not be located in the Application file and have therefore not been considered. Additionally, reference HV,

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which appears on the IDS filed 5/31/2005, has not been considered because this reference is not a complete reference and the accompanying artifact (CD filed with the IDS of 5/31/2005 as an artifact) that is purported to contain the remainder of this reference is not proper subject matter for submission as a CD, in accordance with 37 CFR 152(e).

Claim Objections

4. Applicant is advised that should claim 2 be found allowable, claim 5 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

5. Claims 1-8 and 10 are objected to because of the following informalities: As stated in MPEP § 2173.05(s) in regards to references to figures and tables in claims:

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fresso.

In the instant case, there is no reason that the claimed polynucleotide that encodes amino acids contained in Figure 1 or comprises contiguous nucleotides from the coding region of the nucleic acid sequence in Figure 1, cannot be identified in the claims by the appropriate sequence identifier (SEQ ID NO:). This is not an exceptional circumstance and the SEQ ID NO: is a practical way to define the invention in words. Appropriate correction is required.

6. Claim 1 is objected to because of the following informalities: Claim 1 recites, "selected from a group consisting of:...". which is improper format for a Markush type claim, as it should properly recite, "selected from the group consisting of:...". Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 7-8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites, "a polynucleotide encoding amino acids from about 1 to about 188 of the amino acid sequence contained in Figure 1." However, the skilled artisan cannot determine the metes and bounds of what is being claimed because there is no context for determining what is being claimed by a polynucleotide encoding amino acids " from about 1 to about 188 of the amino acid

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sequence in Figure 1". The skilled artisan cannot determine, from the present claim terminology, what amino acids are required to be encoded by the claimed polynucleotide. Does the claimed polynucleotide encode about 1 amino acid of the amino acid sequence contained in Figure 1, and if its is only about 1, which is it? The claim language "from about 1 to about 188 of the amino acid sequence in Figure 1," for example, does not limit this amino acid to the first encoded amino acid. Does the claimed polynucleotide encode about 188 amino acids of the amino acid sequence contained in Figure 1 or does the polynucleotide encode some number of amino acids that is between 1 and 188 of the amino acid sequence contained in Figure 1, and if so which ones? Claims 7-8 and 10 are rejected due to their dependence on a rejected claim.

9. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 is drawn to an isolated nucleic acid molecule comprising a polynucleotide that encodes a polypeptide wherein, "said polypeptide has an amino acid sequence selected from the group consisting of amino acids from about 1 to about 188 of the amino acid sequence contained in Figure 1." However, the skilled artisan cannot determine the metes and bounds of what is being claimed because the amino acid sequence of the polypeptide that is encoded by the claimed polynucleotide, cannot be determined from the present claim terminology. The skilled artisan cannot determine what amino acid sequence, selected from the group consisting of amino

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acids from about 1 to about 188 of the amino acid sequence contained in Figure 1, is being claimed. Does the claimed polypeptide have about 1 amino acid of the amino acid sequence contained in Figure 1, and if its is only about 1, which one is it? The claim language "amino acids from about 1 to about 188 of the amino acid sequence contained in Figure 1," for example, does not limit this amino acid to the first encoded amino acid. Does the claimed polypeptide have about 188 amino acids of the amino acid sequence contained in Figure 1 or does the claimed polypeptide have some number between 1 and 188 amino acids of the amino acid sequence contained in Figure 1, and if so which ones?

10. It is suggested to Applicant that inclusion of a particular SEQ ID NO: for the instantly claimed polynucleotide and claim language which provides a context for the numbers included in the claims, so that the particular amino acids that are required to be encoded by the claimed polynucleotide can be specifically identified, could be remedial in overcoming the rejections above.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1, 6-8 and 10 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 1 is broadly drawn to an isolated nucleic acid molecule comprising a polynucleotide selected from the group consisting of (a) a polynucleotide encoding amino acids from about 1 to about 188 of the amino acid sequence contained in Figure 1; (b) a polynucleotide encoding amino acids from about 2 to about 188 of the amino acid sequence contained in Figure 1; (c) the polynucleotide complement of the polynucleotide of (a) or (b); and (d) a polynucleotide at least 90% identical to the polynucleotide of (a), (b) or (c). Claim 6 is broadly drawn to an isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide, wherein except for at least one conservative amino acid substitution, addition or deletion, said polypeptide has an amino acid sequence selected from the group consisting of (a) amino acids from about 1 to about 188 of the amino acid sequence in Figure 1 and (b) amino acids from about 2 to about 188 of the amino acid sequence in Figure 1.

Claim 1 reads broadly on a vast genus of polynucleotides that encode about 1 or about 2 to about 188 of the amino acid sequence contained in figure 1 (which is SEQ ID NO: 2), the complement of a or b, and any polynucleotide that is at least 90% identical to a or b or the complement of a or b. However, the specification as filed does not provide an adequate written description of the broad genus of polynucleotides claimed that can be 90% identical to a or b, commensurate with the breadth of what is claimed, that will be any polynucleotide that can be 90% identical to a or b that will encode about

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1 or about 2 to about 188 of the amino acid sequence contained in figure 1. The skilled artisan cannot immediately envision that Applicant was in possession of this broadly claimed genus.

Claim 6 reads broadly on a vast genus of polynucleotides that encode any polypeptide that, except for at least 1 conservative amino acid substitution, addition or deletion, which can be any conservative amino acid substitution, addition or deletion, will encode amino acids from about 1 or about 2 to about 188 of the amino acid sequence in figure 1. However, the specification as filed does not provide an adequate written description of the broad genus of polynucleotides claimed that encode polypeptides wherein except for at least 1 conservative amino acid substitution, addition or deletion, which can be any conservative amino acid substitution, addition or deletion, the polynucleotide will encode amino acids from about 1 or about 2 to about 188 of the amino acid sequence in figure 1. The skilled artisan cannot immediately envision that Applicant was in possession of this broadly claimed genus.

The specification as filed provides no examples of polynucleotide that are less than 100% identical to the claimed polynucleotide and only general guidance in regard to how one of skill in the art would identify a polynucleotide that was of a given percent identity with another polynucleotide using a computer alignment. The specification provides only general guidance concerning how one skilled in the art would recognize, generally, what amino acid substitutions, additions or deletions would be conservative, generally, in polypeptides. The specification provides no specific guidance in regards to the structure of a polynucleotide that can be 90% identical to the polynucleotide claimed

in a and b of claim 1, wherein any 10% of the nucleobases in the polynucleotide can be non-identical, that will still function commensurate with the breadth of what is claimed, that will encode about 1 or about 2 to about 188 of the amino acid sequence contained in figure 1. Likewise, the specification provides no specific guidance that would lead the skilled artisan to the structure of a polynucleotide that encodes a polypeptide as claimed in a and b of claim 1, wherein except for at least 1 conservative amino acid substitution, addition or deletion, which can be any conservative amino acid substitution, addition or deletion, the polynucleotide will encode amino acids from about 1 or about 2 to about 188 of the amino acid sequence in figure 1. The specification does not provide a correlation between the structures of the claimed polynucleotides and the functions as claimed, wherein these polynucleotides are required to encode amino acids.

Additionally, the specification as filed does not disclose any distinguishing identifying characteristics of the claimed polynucleotides that can be 90% identical to the polynucleotides set forth in a and b of claim 1, that would indicate that applicant was in possession of this broadly claimed genus, commensurate with what is now claimed, that will encode about 1 or about 2 to about 188 of the amino acid sequence contained in figure 1. Likewise, the specification as filed does not disclose any distinguishing identifying characteristics of the claimed polynucleotides that encode polypeptides which, except for at least 1 conservative amino acid substitution, addition or deletion, which can be any conservative amino acid substitution, addition or deletion, the polynucleotide will encode amino acids from about 1 or about 2 to about 188 of the amino acid sequence in figure 1.

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The general guidance and examples provided by the specification are insufficient to indicate possession of the broadly claimed genera of polynucleotide as claimed. The specification does not provide the specific guidance that would be required to reasonably lead one of skill in the art to the instant invention or that would allow the skilled artisan to recognize that Applicant was in possession of the instant invention, commensurate with what is now claimed and state of the art cannot provide the required specific guidance

MPEP § 2163[R-2] I. states:

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., > Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); < Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116.

The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc., 935 F.2d at 1563-64, 19 USPQ2d at 1117.

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. > Enzo Biochem, 323 F.3d at 964, 63 USPQ2d at 1613.<

In the instant case, Applicant has not provided adequate written description of their invention because the specification does not convey, with reasonable clarity to those of skill in the art, as of the filing date sought, that applicant was in possession of

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the invention now claimed. Applicant has not shown how the invention was "ready for patenting" such as by the disclosure of the structure of a polynucleotide that was 90% identical to the polynucleotides set forth in a and b of claim 1, that will function commensurate with the breadth of what is now claimed (that shows that the claimed invention was complete) or by the disclosure of a polynucleotide that encoded a polypeptide wherein, except for at least 1 conservative amino acid substitution, addition or deletion, which can be any conservative amino acid substitution, addition or deletion, the polynucleotide will encode amino acids from about 1 or about 2 to about 188 of the amino acid sequence in figure 1. Neither has Applicant described any distinguishing identifying characteristics sufficient to show that the applicant was in possession of the broad genera of polynucleotides, as claimed.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-5, 7-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kumar et al 2000 (Reference BB on PTO Form 1449 filed 7/25/03 in this Application). Claim 1 is drawn to an isolated nucleic acid molecule comprising a polynucleotide selected from the group consisting of the polynucleotide sequences

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listed as a-d. Dependent claims 2-5, 7-8 and 10 set forth further limitations of the nucleic acid of claim 1 wherein it comprises about a certain number of contiguous nucleotides of from the coding region identified or of the nucleic acid sequence of SEQ ID NO: 1 (*as determined by the Examiner from the specification at sections [0006-0007], which indicates that the polypeptide identified in figure 1 is SEQ ID NO: 2 and the nucleotide sequence identified in figure 1 is SEQ ID NO:1*"), wherein the polynucleotide is a cDNA, is comprised in a vector and wherein that vector is comprised in a host cell. Kumar et al. is applied as prior art under 35 U.S.C. 102(b) because, as indicated on the Table of Contents of Vol. 275, No. 4 of the Journal of Biological Chemistry (attached for Applicant's convenience), the Kumar et al. reference was publically available (online in Electronic Form) as of January 21, 2000, which is over 1 year prior to the filing of Applicant's provisional Application 60/624,062.

Kumar et al. disclose the isolation and characterization of a novel tumor necrosis factor a inducible gene, SCC-S2, that is an isolated nucleic acid that comprises a polynucleotide that encodes all of the amino acids contained in instant Figure 1, that further comprises about 10 nucleotides from the coding region identified or contained in Figure 1 and about 50 or about 100 contiguous nucleotides from the coding region of the nucleic acid sequence in or contained in Figure 1 (as required by dependent claims 2-5), that is a cDNA that is comprised in a recombinant vector that is comprised in a host cell (See: pg. 2973, Abstract; pg. 2974, Figure 1 and legend; pg. 2976, "transient transfection and immunoblotting"). Therefore, Kumar et al. anticipate the instant invention as set forth in claims 1-5, 7-8 and 10.

15. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Patel et al 1997 (Reference BK on PTO Form 1449 filed 7/25/03 in this Application). Claims 1-5 are relied upon as above. Claim 6 is drawn to an isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide wherein, except for at least one conservative amino acid substitution, addition or deletion, the polypeptide is selected from the group consisting of the polynucleotide sequences listed as a and b in claim 1.

Based on the 112nd paragraph rejection of claims 1 and 6 (above), a reasonable interpretation considers that a reference which discloses a polynucleotide that encodes any amino acids from about 1 of the amino acids to about 188 of the amino acids of the amino acid sequence acid sequence contained in figure 1 would apply as prior art. The following prior art is applied.

Patel et al. disclose an isolated nucleic acid comprising a polynucleotide that encodes from about 1 of the amino acid sequence contained in instant Figure 1 to about 188 of the amino acid sequence contained in instant Figure 1 wherein they disclose the size determination, by Northern blot, of expressed SCC-S2 mRNA and state that the SCC-S2 mRNA transcript is approximately 2.3 kb in length (pg. 200, discussion, 1st paragraph). The SCC-S2 mRNA transcript identified by Patel et al. is considered isolated in that is shown on a northern blot (see figure 2, pg. 200). The SCC-S2 mRNA transcript identified by Patel et al., in being a transcript of 2.3 kb, would inherently comprise the claimed isolated nucleic acid that comprises a polynucleotide that encodes amino acids from about 1 of the amino acid sequence contained in instant

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Figure 1 to about 188 of the amino acid sequence contained in instant Figure 1, that further comprised about 10 nucleotides from the coding region identified or contained in Figure 1 and about 50 or about 100 contiguous nucleotides from the coding region of the nucleic acid sequence in or contained in Figure 1 (as required by dependent claims 2-5), because the polynucleotide contained in Figure 1 is disclosed as a 1915 bp cDNA. An SCC-S2 mRNA transcript of 2.3 kb, absent evidence to the contrary, would encode at least one conservative amino acid substitution, addition or deletion based on the presence of 800 additional base pairs along its length of 2300 bp (as compared to the length of the instantly claimed polynucleotide that is about 1500 nucleotides (as set forth in section [0007 of the specification as filed, nucleotides 397 to 1915 of SEQ ID NO: 1). because there will be at least one 3 bp codon in the 800 bp that are not shared between the transcript disclosed by Patel et al. and the instantly claimed polynucleotide that encodes about 1 of the amino acids of SEQ ID NO: 2 that will constitute a conservative addition or deletion because it will not change the activity of the polypeptide encoded by the claimed polynucleotide). Therefore, Patel et al. anticipate the instant invention as set forth in claims 1-6.

16. Claims 1-5 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Horrevoets et al. (Reference AQ on PTO Form 1449 filed 7/25/03 in this Application). Claims 1-5 and 7-8 are relied upon as above.

Horrevoets et al. disclose the isolation and characterization of a novel gene that is responsive to tumor necrosis factor which they identify as GG2_1, that is an isolated

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nucleic acid that comprises a polynucleotide that encodes amino acids from about 1 of the amino acid sequence contained in instant Figure 1 to about 188 of the amino acid sequence contained in instant Figure 1, that further comprises about 10 nucleotides from the coding region identified or contained in Figure 1 and about 50 or about 100 contiguous nucleotides from the coding region of the nucleic acid sequence in or contained in Figure 1 (as required by dependent claims 2-5), that is a cDNA that is comprised in a recombinant vector (See: pgs. 3420, top of col. 1; pg. 3422, col. 2, "cloning and analysis of 5 novel cytokine responsive transcripts"; pg. 3424, col. 2, top). Therefore, Horrevoets et al. anticipate the instant invention as set forth in claims 1-5 and 7-8.

17. Based on the 112 2nd paragraph rejection of claims 1 and 6 (above), a reasonable interpretation considers that a reference which discloses a polynucleotide that encodes any amino acids from about 1 of the amino acids to about 188 of the amino acids of the amino acid sequence acid sequence contained in figure 1 would apply as prior art. The following prior art is applied.

18. Claims 1-3, 5-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lamerdin et al. 1998 (Direct submission: AC005339). Claims 1-2, 5-6 and 8 are relied upon as above.

Lamerdin et al. disclose genomic cosmid R33729 which is an isolated polynucleotide encoding amino acids from about 106 of the amino acid sequence

contained in figure 1 (which is SEQ ID NO: 2). The cosmid of Lamerdin et al. comprises about 10 and about 50 contiguous nucleotides from the coding region of SEQ ID NO: 1 (see attached alignment, for example, nucleotides that encode amino acids from position 32 to positions 46 are about 50 contiguous nucleotides). The isolated polynucleotide of Lamerdin et al. encodes a polypeptide wherein except for at least one conservative amino acid substitution, addition or deletion said polypeptide has an amino acid sequence selected from the group consisting of amino acids from about 1 (and about 2) to about 188 of SEQ ID NO: 2 (the amino acid sequence contained in Figure 1) (see attached alignment for depiction of conservative amino acid substitutions). Therefore, Lamerdin et al. anticipate the instant invention as set forth in claims 1-3, 5-6 and 8.

19. Claims 1, 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Goltsev et al. 1997 (Journal of Biological Chemistry, Vol. 272 (32): 19641-19644). Claims 1, 6 and 7 are relied upon as above.

Goltsev et al. disclose the cloning, by reverse transcription, of nucleic acid sequences that encode mouse α and β CASH proteins from expressed mRNA (thereby disclosing cDNA clones) (pg. 19641, bottom of col. 1; col. 2, "Experimental Procedures"). The isolated polynucleotides Goltsev et al. comprise a polynucleotide encoding amino acids from about 19 of the amino acid sequence contained in figure 1 (see the amino acid alignment provide by Applicant in Figure 2 which depicts the about 19 amino acids encoded by mouse α and β CASH that are also encoded by the

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instantly claimed polynucleotide). The isolated polynucleotide of Goltsev et al. encodes a polypeptide wherein except for at least one conservative amino acid substitution, addition or deletion the polypeptide of Goltsev et al. has an amino acid sequence selected from the group consisting of amino acids from about 19 of SEQ ID NO: 2 (the amino acid sequence contained in Figure 1) (see alignment in Applicant's Figure 2 for depiction of conservative amino acid substitutions between mouse CASH and SCC-S2). Therefore, Goltsev et al. anticipate the instant invention as set forth in claims 1 and 6-8.

Conclusion

20. No claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

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Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba

Jane Zana
TC1600

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78 503 52.3 1171 9 AF271774 Homo sapi
79 484.5 50.4 2156 3 AK112519 Ciona int
80 401 41.7 829 3 CQ580257 Sequence
81 401 41.7 1821 3 AY095033 Drosophila
82 383.5 39.9 4406 6 CQ580256 Sequence
83 383.5 39.9 175118 3 AC010842 Drosophila
84 383.5 39.9 188272 3 AC005639 Drosophila
85 383.5 39.9 295225 3 AC003461 Drosophila
86 358 37.2 69208 2 AC020466 Drosophila
87 292 30.4 714 6 BD146713 Primer for
88 292 30.4 714 6 AX866651 Sequence
89 292 30.4 1602 6 BD160707 Primer for
90 292 30.4 1602 6 AX884081 Sequence
91 292 30.4 1602 9 AK024161 Homo sapi
92 250 26.0 340 6 AX898564 Sequence
93 250 26.0 340 6 BD034097 Sequence
94 166 17.3 252 6 AX898571 Sequence
95 166 17.3 252 6 BD034104 Sequence
96 112 11.6 301130 1 AE016763 Escherich
97 106 11.0 1329 3 AK116070 Ciona int
98 105.5 11.0 303414 1 AE015938 Clostridi
99 104.5 10.9 3408 8 AF378568 Bremonothe
100 104.5 10.9 110000 8 AF016816_3 Continuation (4 of 8)
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ALIGNMENTS

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RESULT 1
AF070671 1892 bp mRNA linear PRI 21-JUN-1999
LOCUS Homo sapiens TNF-induced protein GG2-1 mRNA, complete cds.
DEFINITION AF070671
ACCESSION AF070671
VERSION AF070671.1 GI:3978237
KEYWORDS Homo sapiens (human)
SOURCE Homo sapiens
ORGANISM Homo sapiens
Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
1 (bases 1 to 1892)
Horrevoets,A.J., Fontijn,R.D., van Zonneveld,A.J., de Vries,C.J.,
ten Cate,J.W. and Pannekoek,H.
Vascular endothelial genes that are responsive to tumor necrosis
factor-alpha in vitro are expressed in atherosclerotic lesions,
including inhibitor of apoptosis protein-1, stannin, and two novel
genes
JOURNAL Blood 93 (10), 3418-3431 (1999)
MEDLINE 99252096
PUBMED 10233894
REFERENCE 2 (bases 1 to 1892)
AUTHORS Horrevoets,A.J.G., Fontijn,R.D. and Pannekoek,H.
TITLE Direct Submission
JOURNAL Submitted (05-JUN-1998) Biochemistry, Academic Medical Center,
Meibergdreef 15, Amsterdam 1105 AZ, The Netherlands
FEATURES
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1..1892
Location/Qualifiers
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/cell_type="endothelial"
/tissue_type="umbilical vein"
98..664
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/protein_id="AAC83229.1"
/db_xref="GI:3978238"
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LYNPFNGFKHLQLKCLDGINLMDENI"
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ORIGIN

Alignment Scores:

Pred. No.: 9.11e-76 Length: 1892

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Score: 954.00 Matches: 187
Percent Similarity: 99.47% Conservative: 0
Best Local Similarity: 99.47% Mismatches: 1
Query Match: 99.17% Indels: 0
DB: Gaps: 0
US-10-627-571-2 (1-188) x AF070671 (1-1892)
QY 1 MetAlaThrAspValPheAsnSerLysAsnLeuAlaValGlnAlaGlnLysLeuLeu 20
Db 98 ATGGCCACAGAGTCTTAAATTCCTGCGGCTTCCAGGCAACAAAGAGATCTTG 157
QY 21 GlyLysMetValSerLysSerLeuAlaThrLeuLeuAspAspThrSerSerGluVal 40
Db 158 GGTAATAATGGTCTCAATATCCATCGCCACCATTAATAGACGACACAGTAGTAGG 217
QY 41 LeuAspGluLeuValArgValThrArgGluThrGlnAsnLysLysGluAlaGluLys 60
Db 218 CTGGATGAGCTCTACAGAGTGACCGAGGAGTACACCCAAACAAAGAGGAGGAGAG 277
QY 61 LysIleLysAsnLeuIleLysThrValIleLysLeuAlaIleLeuTyArgAsnGln 80
Db 278 ATCATCAGAACCTCATCAGACAGTCTCAGCTGGCCATTTCTTAGGAATATATCAG 337
QY 81 PheAsnGlnAspGluLeuAlaLeuMetGluLysPheLysLysValHisGlnLeuAla 100
Db 338 TTTAATCAAGATGAGCTAGCTAGTATGATGAGAAATTTAAGAGAAAGTTTCATCAG 397
QY 101 MetThrValValSerPheHisGlnValAspThrPheAspArgAsnValLeuSerArg 120
Db 398 ATGACCGGGTGGTTCATGATGAGTATATACCTTTGACCGGATGTGTATCCAGG 457
QY 121 LeuLeuAsnGluCysArgGluMetLeuHisGlnIleLeuGlnArgHisLeuThrAlaLys 140
Db 458 CTGTTAATGATGAGAGAGATGCTGACCAATCATTCAGCCACCTCTACTGCCAAG 517
QY 141 SerHisGlyArgValAsnAsnValPheAspHisPheSerAspCysGluPheLeuAla 160
Db 518 TCACATGACGGTAAATATGCTCTTTGATCATTTTTCAGATTGGAATTTTGGCTGCC 577
QY 161 LeuThrAsnProPheGlyAsnPheLysProHisLeuGlnLysLeuCysAspGlyLeu 180
Db 578 TTGTATATCTCTTTGGGAATTTTAAACCCCACTTACAAAACCTATGTGTATGATCAAC 637
QY 181 LysMetLeuAspGluGluAsnIle 188
Db 638 AAAATGTTGGATGAGAGACATA 661
RESULT 2
BD156880 1921 bp DNA linear PAT 17-JAN-2003
LOCUS Primer for synthesizing full-length cDNA and use thereof.
DEFINITION BD156880
ACCESSION BD156880
VERSION BD156880.1 GI:27862638
KEYWORDS JP 2002191363-A/11723
SOURCE Homo sapiens (human)
ORGANISM Homo sapiens
Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
1 (bases 1 to 1921)
Ota,T., Isogai,T., Nishikawa,T., Hayaishi,K., Saito,K., Yamamoto,J.,
Ishii,S., Sugiyama,T., Wakamatsu,A., Nagai,K. and Otsuki,T.
Primer for synthesizing full-length cDNA and use thereof
Patent: JP 2002191363-A 11723 09-JUL-2002;
HELIX RESEARCH INSTITUTE
OS Homo sapiens (human)
PN JP 2002191363-A/11723
PF 09-JUL-2002
PI TOSHIO OTA, TAKAO ISOGAI, TETSUO NISHIKAWA, KOJI HAYASHI, KAORU
PI SAITO,
PI JUNICHI YAMAMOTO, SHIZUKO ISHII, TOMOYASU SUGIYAMA, AI WAKAMATSU,
PI KEIICHI NAGAI, TETSUJI OTSUKI
```

Where differences are found these are annotated as variations together with a note of the overlapping clone name. Note that variation annotation may not be found in the sequence submission corresponding to the overlapping clone, as we submit sequences with only a small overlap as described above.

This sequence was finished as follows unless otherwise noted: all regions were either double-stranded or sequenced with an alternate chemistry or covered by high quality data (i.e., phred quality >= 30); an attempt was made to resolve all sequencing problems, such as compressions and repeats; all regions were covered by at least one plasmid subclone or more than one M13 subclone; and the assembly was confirmed by restriction digest, except on the rare occasion of the clone being a YAC.

The following abbreviations are used to associate primary accession numbers given in the feature table with their source databases: Em, EMBL; Sw, SWISSPROT; Tr, TrEMBL; Wp, WORMPEP; Information on the WORMPEP database can be found at http://www.sanger.ac.uk/Projects/C_elegans/wormpep. Zebrafish pUC subclones occasionally display inconsistency over the length of mononucleotide A/T runs and conserved TA repeats. Where this is found the longest good quality representation will be submitted.

Repeat names beginning 'Dr' were identified by the Recon repeat discovery system (Zhirong Bao and Sean Eddy, submitted), and those beginning 'dr' were identified by Rick Waterman (Stephen Johnson lab, WashU). For further information see http://www.sanger.ac.uk/Projects/D_reio/fishmask.shtml CH211-12A1 is from a CHORI-211 BAC library

VECTOR: pTARBAC2.1.

Location/Qualifiers

1. .189797
/organism="Danio rerio"
/mol_type="genomic DNA"
/db_xref="taxon:7955"
/clone="CH211-12A1"
/clone_lib="CHORI-211"

ORIGIN

Alignment Scores:

Pred. No.: 4,07e-42 Length: 189797
Score: 600.00 Matches: 106
Percent Similarity: 84.4% Conservative: 46
Best Local Similarity: 58.89% Mismatches: 28
Query Match: 62.37% Indels: 0
DB: 5 Gaps: 0

US-10-627-571-2 (1-188) x BX927313 (1-189797)

Qy 6 PheAenSerLysAenLeuAlaValGlnAlaGlnLysLysLysLysMetValSer 25
Db 167674 TTCAATTCCTCAAGTTTGGCCCTTCAGGCTCAAGAGAGATTTTGGTAAATGGCCACC 167615
Qy 26 LysSerLeuAlaThrLeuLeuLeuLeuLeuLeuLeuLeuLeuLeuLeuLeu 45
Db 167614 ATGGCCGTCGCGAATCTCTTACACGACGACACGACGACGATTCGACGAACTTAC 167555
Qy 46 ArgValThrArgGluTyrThrGlnAenLysLysLysLysLysLysLysLysLys 65
Db 167554 AGGCCAGTCGAGATACACCAAGACGACGACGACGACGACGACGACGACGAC 167495
Qy 66 IleLysThrValLysLysLysLysLysLysLysLysLysLysLysLysLysLys 85
Db 167494 ATCAAGATCGCTCTGAAGATTGGCATTTCTACCGGACCCACGATTCAGTCTGAGGAG 167435
Qy 86 LeuAlaLeuMetGluLysPheLysLysLysLysLysLysLysLysLysLysLys 105
Db 167434 ATGGACAGTCGCGCTTCAAAAGAGATGAACACGACGACGACGACGACGACGAC 167375
Qy 106 PheHisGlnValAspTyrThrPheAspArgAenValLeuSerArgLysAenGluCys 125
Db 167374 TTTTATGAAGTGGAGTACATTCACGACGACGACGACGACGACGACGACGACGAC 167315
Qy 126 ArgGluMetLeuHisGlnLysLysLysLysLysLysLysLysLysLysLysLys 145

Db 167314 AGAGACCTTCTCCAGGAGTGGTGGAGCACCACCTTGACCATCGGTCCACGGCGGATT 167255
Qy 146 AenAenValPheAspHisPheSerAspCysGluPheLeuAlaLeuTyrAsnProPhe 165
Db 167254 GACCAAGTTTCAACCATTCGCCGATTCGATTCCTCCAGGAGTGTACGCCCATCT 167195
Qy 166 GlyAenPheLysProHisLeuGlnLysLeuCysAspGlyLysMetLeuAenGlu 185
Db 167194 GAAGACTACAGATTAACTTGAAGAGATCTGCGATGGATTAACAACAATCTCTAGACGAG 167135

RESULT 45

AC005339

LOCUS

DEFINITION

AC005339

VERSION

AC005339.1

KEYWORDS

HTG.

SOURCE

Homo sapiens

ORGANISM

Homo sapiens

REFERENCE

AUTHORS

TITLE

JOURNAL

REFERENCE

AUTHORS

TITLE

JOURNAL

COMMENT

FEATURES

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repeat_region complement(5239..5545)
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repeat_region complement(13881..14172)
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repeat_region 20720..21034
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complement(21329..21549)
/notes="BLASTN similarity to 242385 (1..220); match: 0.97,
score: 9.7e-83; database searched: est; H. sapiens partial
cDNA sequence"
21389..21554
/notes="predicted exon, program: grail2exons_human_1.3,
frame: 1, quality: excellent, score: 77.000"
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22943..23243
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23246..23404
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complement(24790..25329)
/notes="DDB similarity to overlapping ESTs:
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identity.-(25329..25201) A477268 zu43c12.r1 Soares ovary
tumor NBHOT Homo sapiens cDNA clone 740758 5'; (221..349);
100% identity.-(25061..24842) A477268 zu43c12.r1 Soares
ovary tumor NBHOT Homo sapiens cDNA clone 740758 5';
(350..570); 98% identity.-(24792..25272) N32339 yw82g08.s1
Homo sapiens cDNA clone 258782 3'. Score: 925 Identity:
476/480 (99%) (25329..25028) AA579149 nf28a04.s1
NCI CGAP P11 Homo sapiens cDNA clone IMAGE:915054;
(134..434); 99% identity.-(24790..25061) AA477269
zu43c12.s1 Soares ovary tumor NBHOT Homo sapiens cDNA
clone 740758 3'; (272..1); 100% identity.-(Additional EST
matches:
AA581955, AA467935, AI038745, AI041764, T24716"
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32121..32185))
/notes="Hypothetical partial human protein"
/evidence=not experimental
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CDS

Alignment Scores:
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Score: 593.00 Matches: 106
Percent Similarity: 79.14% Conservative: 42
Best Local Similarity: 56.68% Mismatches: 39

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Query Match: 61.64% Indels: 0
DB: 9 Gaps: 0
US-10-627-571-2 (1-188) x AC005339 (1-32360)

QY 2 AlaThrAspValPheAsnSerLysAsnLeuAlaValGlnAlaGlnLysLysLeuGly 21
DB 19112 GCCATGGACACCTTCAGACCAAGAGCTGGCTCTGCGGCGCAGAAGAGCTCCTGAGT 19171
QY 22 LysMetValSerLysSerIleAlaThrThrLeuIleAspThrSerSerGluValLeu 41
DB 19172 AGATGGCTGCCAGGCGATGGTGGCGCTGGTGGATGACACCAAGAGCTGAGGTGCTG 19231
QY 42 AspGluLeuTyrArgValThrArgGluTyrThrGlnAsnLysLysGluAlaGluLysLys 61
DB 19232 GATGAGCTGTACCGCGCCACAGGAGTTTCAGCGGCGCGGAGGAGGCCCGAGAGATG 19291
QY 62 IleLysAsnLeuLysThrValLysLysLeuAlaIleLeuTyrArgAsnAsnGlnPhe 81
DB 19292 CTCAGAAGCTGGTCAAGGTGGCCCTGAAGCTGGGACTGCTGCTGGTGGGACCAAGT 19351
QY 82 AsnGlnAspGluLeuAlaLeuMetGluLysPheLysLysValHisGlnLeuAlaMet 101
DB 19352 GCGGTGAGAGCTGGCGCTGTGGCGGCTTCGCGCACCGGCGCGCTGCTGGCCATG 19411
QY 102 ThrValValSerPheHisGlnValAspTyrThrPheAspArgAsnValLeuSerArgLeu 121
DB 19412 ACGGCGGTGAGCTTCACCGAGTGGACTTCACCTTCGACCGCGCGGTGCTGGCCCGGG 19471
QY 122 LeuAsnGluCysArgGluMetLeuHisGlnIleLeuArgHisLeuThrAlaLysSer 141
DB 19472 CTGCTCGAGTGGCGGACCTGCTGCACCGCGCGGTGGTCCCTGACCGCCCAAGTCC 19531
QY 142 HisGlyArgValAsnAsnValPheAspHisPheSerAspCysGluPheLeuAlaLeu 161
DB 19532 CACGCCCGCATCAACCGCTGTTCGGCCACCTAGCCGACTGCGACTTCTGGCTGCGCTC 19591
QY 162 TyrAsnProPheGlyAsnPheLysProHisLeuGlnLysLeuCysAspGlyIleAsnLys 181
DB 19592 TACGCCCGCGCGAGCCCTACCGCTCCACCTGCGCAGGATCTGCGAGGGGCTGGGCCGG 19651
QY 182 MetLeuAspGluGluAsnIle 188
DB 19652 ATGCTGGACGAGGGCAGCTC 19672

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Search completed: July 28, 2005, 20:50:53
Job time : 4523 secs